K132623

DEC 19 2013

5.0 510(k) Summary

As required by the Safe Medical Devices Act of 1990, coded under Section 513, part (1)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Date Prepared: August 21, 2013

Applicant:
Medtronic CoreValve, LLC
1851 E. Deere Ave.
Santa Ana, CA 92705
U.S.A.
Establishment Registration No. 2025587

Contact Person:
Monica Hernandez-Soto
Regulatory Affairs Specialist
Phone: (707) 591-2285
Fax: (707) 573-4443
E-mail:Monica.hernandez-soto@medtronic.com

Subject Device Name:

Device Trade Name: Medtronic Confida™ Brecker Curve™ Guidewire

Common Name: Guidewire

Classification Name: Wire, Guide, Catheter

Classification: Class II, 21 CFR 870.1330

Product Code: DQX

Predicate Device(s):

- Medtronic Archer™ Super Stiff Guidewire (K101339, cleared Aug. 31, 2010), manufactured by Medtronic, Inc.
- Toray TORAYGUIDE™ Guidewire (K042370, cleared Dec.17, 2004), manufactured by Toray Industries, Inc.

Device Description: The Medtronic Confida™ Brecker Curve™ Guidewire is manufactured of 304 stainless steel and is polytetrafluoroethylene (PTFE) coated, which is consistent with guidewires presently in commercial distribution and with the same intended use. The device diameter is 0.035 inches and 260 cm in length. The distal end of the Medtronic Confida™ Brecker Curve™ Guidewire is comprised

of a preformed curved tip. The loop configuration has a 540° curved tip which is 30 mm in width and aids in anchoring of the distal spring tip during diagnostic and interventional procedures, including TAVI.

Statement of Intended Use: The Medtronic Confida™ Brecker Curve™ Guidewire is intended to to facilitate the placement of devices during diagnostic and interventional procedures.

Statement of Indications for Use: The Medtronic Confida™ Brecker Curve™ Guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve implantation (TAVI).

Comparison of Indications for Use to Predicate Devices: The Indications for Use of the Medtronic Confida™ Brecker Curve™ Guidewire is within the scope of the Indications for Use of both predicate devices. While the Indications for Use are different between the subject device and the predicate devices, the differences do not raise any new issues of safety and effectiveness of the device or change the intended use of the device.

Contraindications: The Medtronic Confida™ Brecker Curve™ Guidewire is contraindicated for patients presenting with an intolerance to anticoagulation therapy and unheparinized patients.
The Guidewire is contraindicated for use in the coronary arteries and in the cerebrovasculature.

Comparison of Technological Characteristics to Predicate Devices: The Medtronic Confida™ Brecker Curve™ Guidewire has the following similarities to the predicate devices:

- Intended use (all predicates)
- Indications for use (all predicates)
- Target population (all predicates)
- Fundamental scientific technology (all predicates)
- Operating principle (all predicates)
- Packaging materials (all predicates)

- Sterility assurance level and method of sterilization (all predicates)

Summary of Non-Clinical Data:

In order to demonstrate substantial equivalence of the subject device, the Medtronic Confida™ Brecker Curve™ Guidewire, to the predicate devices, the following non-clinical evaluations were performed:

- Visual Inspection
- Overall Length
- Proximal Outer Diameter
- Coil Outer Diameter
- Tip Curve Rotation
- Tip Curve Outer Diameter
- Tip Tensile
- Tip Stiffness
- Loop Compression
- Proximal Stiffness
- Coil Length
- PTFE Coating Adhesion
- PTFE Coating, Simulated Clinical Use
- Corrosion Resistance
- Anchoring
- Usability for Design Validation
- Flexibility
- Torque

Biocompatibility testing was also performed per the requirements of ISO 10993-1:2009 on the Medtronic Confida™ Brecker Curve™ Guidewire as listed below:

- ISO Cytotoxicity Study
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO/USP Pyrogen Study Material Mediated
- ISO Acute Systematic Toxicity Study
- *In Vivo* Thromboresistance
- *In Vitro* Hemolysis Study (Modified ASTM – Extraction Method)

- C3a Compliment Activation
- SC5b-9 Compliment Activation

Packaging and shelf life testing (product and package) was performed on the Medtronic Confida™ Brecker Curve™ Guidewire. In addition, a sterilization validation adoption was performed to ensure the Medtronic Confida™ Brecker Curve™ Guidewire adequately met a Sterility Assurance Level (SAL) of 10^{-6}. The non-clinical evaluations verify the Medtronic Confida™ Brecker Curve™ Guidewire is substantially equivalent to the predicate devices and is adequate for its intended use.

Conclusion:

Based on the information above, the Medtronic Confida™ Brecker Curve™ Guidewire is substantially equivalent in intended use performance, and fundamental scientific technology to the predicate devices, the Archer™ Super Stiff Guidewire (K101339), and Toray TORAYGUIDE™ Guidewire (K042370).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 19, 2013

Medtronic
Ms. Monica Hernandez-Soto
Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, CA 95403

Re: K132623
Trade/Device Name: Confida Brecker Curve Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: November 15, 2013
Received: November 18, 2013

Dear Ms. Hernandez-Soto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indication for Use Statement

510(k) Number (if known): K132623/S001

Device Name:

Medtronic Confida™ Brecker Curve™ Guidewire

Indication for Use:

The Medtronic Confida™ Brecker Curve™ Guidewire is intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve implantation (TAVI).

Prescription Use ____X____ AND/OR Over-The Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

FDA